MBM vs Cap for early esophageal squamous neoplasia.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25667

Source
NTR

Health condition

esophageal squamous cell neoplasia

Sponsors and support

Primary sponsor: AMC Amsterdam
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

1. The percentage of subjects with complete endoscopic removal of the qualifying lesion including pre-randomisation markers at the first ER section;

2. The percentage of subjects with no HGIN or ESCCA in biopsies obtained within 1-cm of the ER scar at 3 months follow-up.

Secondary outcome

1. The number of resections required for complete endoscopic removal of the qualifying lesion;

2. The time required for the initial ER, defined as the time between randomization (after placement of the electrocoagulation markers) and the end of endoscopy (after the complete endoscopic removal of the qualifying lesion (by ER and/or argon plasma coagulation), the treatment of any acute complications (e.g. bleeding), and removal of the ER specimens);

3. The percentage of subjects in whom argon plasma coagulation is required for complete endoscopic removal of the qualifying lesion;

4. The rate of complications, defined as being either “acute” (occurring immediately during the endoscopic procedure), “early” (occurring after the endoscopic procedure but within 48 hours) or “delayed” (occurring after 48 hours);

5. The percentage of subjects with HGIN or ESCCA diagnosed in biopsies/ER-specimens obtained outside the 1-cm margin of the ER scar at 3 months follow-up;

6. The maximum diameter, maximum thickness, and maximum thickness of the submucosal layer of the resection specimens obtained;

7. The costs of the endoscopic resection procedures (based on the time required for the procedure and the cost of disposables).

Study description

Background summary

Endoscopic Resection (ER) for oesophageal highgrade intraepithelial neoplasia (HGIN) or intramucosal cancer (OSCC) with the ER-cap technique is technically difficult, requires submucosal lifting and multiple snares for piecemeal resections. Multi Band Mucosectomy (MBM) is an easy-to-use ER-technique and may be the modality of choice in China, where OSCC is extremely prevalent. We hypothesize that ER-cap and MBM will be equally effective and safe for piecemeal ER in selected patients. Piecemeal ER using the ER-cap, however, is technically more difficult and requires a higher number of disposables. We, therefore, hypothesize that MBM for piecemeal ER will reduce procedure time and cost significantly compared to ER-cap. From a clinical perspective MBM would be a valid alternative to ER-cap if a significant reduction of procedure time and cost were found while maintaining a success rate that is comparable to the ER-cap technique.

Patients with HGIN/OSCC and no signs of submucosal invasion or metastatic disease will be included. Lesions are delineated with electrocoagulation and resected with MBM or ER-Cap.

Study objective

We hypothesize that MBM may have significant advantages over the ER-cap technique, especially in countries where endoscopic expertise is limited.

The aim of this study was to assess the feasibility, safety and effectiveness of the MBM technique for piece-meal ER of early mucosal squamous cell neoplasia of the oesophagus and to randomly compare the MBM technique to the ER-cap technique.

Study design

N/A

Intervention

Endoscopic resection of early esophageal neoplastic lesions by either MBM or ER-cap technique.

Contacts

Public
Meibergdreef 9
David Boerwinkel
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5664571
Scientific
Meibergdreef 9
David Boerwinkel
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5664571

Eligibility criteria

Inclusion criteria

1. Subject is 18-85 years of age, inclusive;

2. A lesion in the squamous esophagus that is visible with white light endoscopy and contains a type 0-IIa, 0-IIb and/or 0-IIc component;

3. After Lugol's staining the lesion and surrounding USLs (i.e. the treatment area; TA) measures ≥2cm and ≤6cm and encompasses ≤2/3 of the circumference;

4. A histological diagnosis of HGIN or ESCCA in biopsies obtained anywhere from the TA;

5. No infiltration into the submucosa or beyond or metastatic disease on endoscopic ultrasound (EUS) and CT-scan of thorax and upper third of the abdomen;

6. Subject is eligible for treatment and follow-up endoscopy and biopsy as required by the protocol;

7. Written informed consent.

Exclusion criteria

1. Any type 0-I or 0-III lesion in the esophagus;

2. Any other neoplastic lesion in the squamous esophagus that is visible with white light endoscopy and can not be included in the TA to meet its maximum size requirements;

3. Any unstained lesion after Lugol's staining elsewhere in the esophagus that can not be included in the TA to meet the its maximum size requirements and contains HGIN or ESCC upon biopsy;

4. Any N or M positive status;

5. Any prior endoscopic resection or endoscopic ablation therapy of the esophagus within a 3 cm range of the TA;

6. Any history of a non-squamous cell cancer of the esophagus, or any history of a squamous cell cancer of the esophagus (any stage) prior to 12 months before screening for this trial;

7. Any prior radiation therapy to the esophagus;

8. Any previous esophageal surgery, except fundoplication without complications (i.e. no slippage, dysphagia, etc).

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2011
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-01-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3092
NTR-old	NTR3246
Other	METC AMC : 09-38/333
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Pouw RE, van Vilsteren FGI, Peters FP, et al. Randomized trial on endoscopic resection-cap versus multiband mucosectomy for piecemeal endoscopic resection of early Barrett's neoplasia. Gastrointest. Endosc. 2011;74(1):35-43.